

coselgiTM  ***melodia***

USER INSTRUCTIONS

CMe15-BTE • CMe10-BTE
CMe5-BTE • CMe3-BTE
Behind-the-ear



YOUR MELODIA™ HEARING AID

(To be filled out by the hearing care professional)

Date: _____

Battery size: _____

☐ CMe15

☐ CMe10

☐ CMe5

☐ CMe3

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SYMBOLS

The following symbols will be used throughout the manual:



WARNING

Messages with this heading indicate serious adverse reactions, potential safety hazards and inadequate performance of device.



CAUTION

Messages with this heading indicate/include information regarding any special care to be exercised.



Non-ionizing radiation.

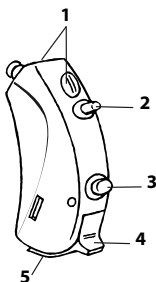


Not for general waste.

THE HEARING AID

The illustration below shows the hearing aid without the ear-set. The choice of ear-set solution depends on your specific needs. Please refer to the separate ear-set user manual.

1. Microphone openings
2. Volume control (optional)
3. Program button
4. On/off switch
5. Battery drawer with nail grip



NOTE

In addition to these user instructions, a separate user manual is provided describing the various ear-set solutions available for your hearing aid: “Ear-sets for Coselgi™ BTE hearing aids”



WARNING

This booklet and the manual “Ear-sets for Coselgi™ BTE hearing aids” contain important information and instructions. Read these booklets carefully before you start using the hearing aid.

NOTE

Your hearing aid, ear-set and accessories may not look exactly as illustrated in this booklet. We also reserve the right to make any changes considered necessary.

Intended use

The Melodia hearing aids are intended as air conduction amplification devices to be used in everyday listening environments.

Indications for use

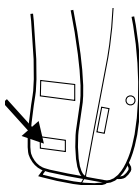
The devices are indicated for individuals with a range of hearing loss severity from minimal (10 dB HL) to severe (90 dB HL) and all hearing loss configurations.

They are to be programmed by licensed hearing care professionals (audiologists, hearing aid specialists, otolaryngologists) who are trained in hearing (re)habilitation.

Description of device

Your hearing aid is used with an ear-set which consists of a tube and an ear-tip, dome or earmold. The hearing aid uses a proprietary wireless technology to enable communication between the left and the right hearing aids, as well as between the hearing aids and its accessories.

Right/left identification



The arrow shows the position of the identification mark (red mark = right and blue mark = left).

Acoustic indicators

The hearing aid may be set to produce tones to indicate the use of certain functions.

Function	Default setting	Alternative setting
Adjusting volume	Tone	Off
Confirming program button use	Clicking sound	Off
Changing program	Tones	Off
Starting up the hearing aid	Tone	Off
Warning about low battery	4 tones	Off

The battery

We recommend **zinc-air batteries**. Use a **size 13** battery for the hearing aid.

To obtain replacement batteries, please consult your hearing care professional. It is important to take note of the expiration date and the recommendations on the battery pack regarding disposal of used batteries.



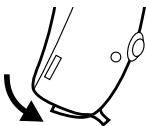
Inserting the battery

Before inserting a new battery into the hearing aid, remember to remove the adhesive tab. Once the tab has been removed, wait 60 seconds before placing the battery into the hearing aid.



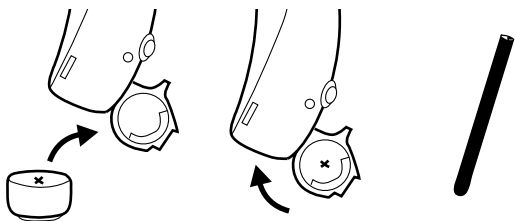
CAUTION

Do not use batteries if there is a sticky residue from the tab or other unwanted substance, as this can cause the hearing aid to malfunction.



Use the nail grip to gently swing the battery drawer open.

Place the battery in the drawer, so that the plus (+) sign on the battery faces upward. You can use the battery magnet provided to steer the battery into place.



If the battery drawer does not close easily, the battery is incorrectly inserted.

When changing battery, it is a good idea to hold the hearing aid over a table.

The hearing aid may be provided with a special battery drawer, helping to secure the battery in the drawer. This type of drawer can be a good choice if the hearing aid is worn by a child.

Low battery indication

An acoustic indicator will sound when the battery is nearly exhausted, unless this function has been disabled (see page 8). We recommend that you always have a spare battery with you.



WARNING

Never leave an exhausted battery in the hearing aid. Exhausted batteries may leak, damaging the hearing aid.

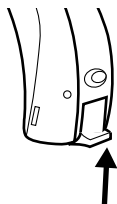


WARNING

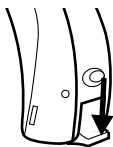
Your hearing aid may stop functioning, for instance if the battery is exhausted. You should be aware of this possibility, in particular when you are in traffic or are otherwise dependent on warning signals.

Turning the hearing aid on and off

The battery drawer of the hearing aid also functions as the on/off switch.



Push the switch upwards to turn on the hearing aid. An acoustic indicator will indicate that the hearing aid has been switched on unless this function has been disabled.



Push the switch downwards to turn off the hearing aid.



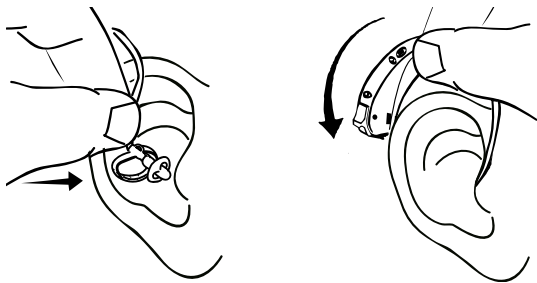
The word "OFF" is clearly visible on the switch when the hearing aid is turned off.

Please remember to turn off the hearing aid when it is not in use. Remove the battery if the hearing aid will not be used for several days.

Positioning the hearing aid

Insert the earpiece in the ear canal while holding the lower part of the tube. It may help to pull the outer ear backwards and upwards with the opposite hand.

Place the hearing aid behind the ear, so that the hearing aid and tube rest comfortably on the ear, close to your head.



The illustrations show an open dome. For further information on ear-tip/dome/earmold types, anchors and procedures, see the separate ear-set user manual provided.

Removing the hearing aid

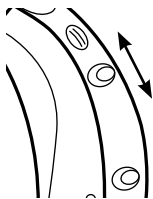
Remove the hearing aid from its position behind the ear.

Carefully pull the earpiece out of the ear canal, while holding the lower part of the tube. If the earpiece is provided with an extraction cord, take hold of this and carefully pull the earpiece out of the ear canal.



Volume adjustment

The hearing aid volume is adjusted automatically in accordance with your sound environment.



Your hearing aid may furthermore be provided with a volume control, shaped like a small lever.

Push the lever upward to gradually raise the volume.

Push the lever downwards to gradually lower the volume.

In the default setting, any volume adjustment will affect both hearing aids.

Each time you operate the volume control, you will hear a beep-tone unless this function has been disabled. When the maximum or minimum adjustment level is reached, a steady tone will sound.



CAUTION

If the volume in the hearing aid is generally too loud or too weak, or the reproduced sounds are distorted, or if you would like any further information, consult your hearing care professional.

To turn off the sound completely

- Keep pressing the volume control lever downwards until the steady tone has sounded

To turn the sound on again

- Press the lever upwards or
- Change listening program

Any adjustment of the volume setting will be canceled when your hearing aid is turned off, or when you change program.

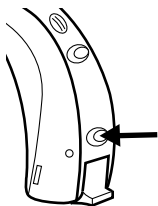
If you wish to have the volume control disabled, please consult your hearing care professional.

Listening programs

Your hearing aid may be provided with several of the following programs. The number of programs available depends on your specific hearing aid.

<input type="checkbox"/> Main	Standard
<input type="checkbox"/> Music	For listening to music
<input type="checkbox"/> TV	For listening to the TV
<input type="checkbox"/> Relax	Attenuates background noise
<input type="checkbox"/> Rearview	Focus on sounds from behind
<input type="checkbox"/> Phone	For listening to the telephone
<input type="checkbox"/> T	In this program you listen via the telecoil (T) and not via the hearing aid microphones (M). The telecoil is used where a loop system is installed. If you activate the telecoil program, you listen to a specific sound source and shut out surrounding sounds.
<input type="checkbox"/> M+T	In this program you listen via the hearing aid microphones (M) and the telecoil (T).

If your needs change over time, the combination of listening programs can be altered.



Switching between the listening programs

Each time you switch to another program, an acoustic indicator will sound unless this function has been disabled.

Program 1: One short beep

Program 2: Two short beeps

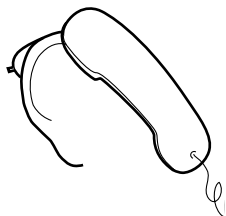
Program 3: Three short beeps

Program 4: One long and one short beep

Program 5: One long and two short beeps

In the default setting, both your hearing aids will be affected when you change programs.

Using a telephone

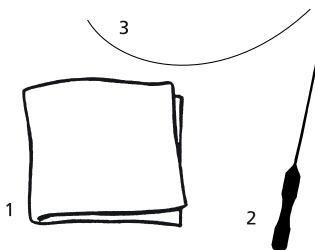


When using a telephone, we recommend that you hold the telephone against your head at an angle above your ear, rather than directly against the ear. If the sound is not optimal, try moving the telephone earpiece to a slightly different position.

CLEANING

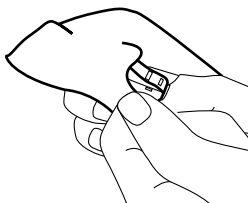
The following cleaning accessories are available for the hearing aid and ear-set*. For cleaning the ear-set, see the user manual "Ear-sets for Coselgi™ BTE hearing aids".

1. Cloth
2. Wax removing tool
3. Cleaning thread



Contact your hearing care professional if you need additional supplies of cleaning accessories.

* Selection depends on ear-set type.



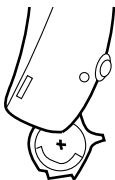
The hearing aid

Clean the hearing aid with the soft cloth after use.



WARNING

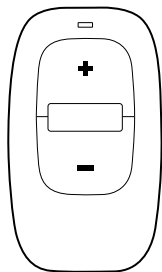
Never use water or cleaning solutions to clean the hearing aid, as this may cause it to malfunction.



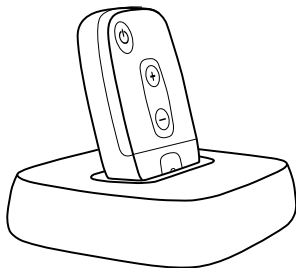
When the hearing aid is not in use, the battery drawer should be left open, to ventilate the hearing aid and allow it to dry.

ACCESSORIES

A number of assistive listening devices may be available for your hearing aid.



RC remote control*



TV-Control*

For help in determining whether you could benefit from a remote control or other accessories, please consult your hearing care professional.

* Not available for CMe3

Audio input

The hearing aid can be furnished with an audio shoe. This allows direct connection to different kinds of accessories (FM and CROS/Bi-CROS systems), as well as external audio equipment (radio, TV, etc.). In this way the sound from, for example, a radio or someone provided with a FM microphone can be sent directly into the hearing aid.

In the standard setting, the hearing aid automatically switches to an audio program when an audio shoe is attached. If you then wish to switch to one of the other programs, you must use the program button on the hearing aid. As soon as you remove the audio shoe, the usual program order is re-established.

On the form below, your hearing care professional can make a note of the audio programs you have access to and where they are located.

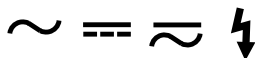
For more information on the use of audio input consult your hearing care professional.

Program	Program order with audio shoe
1	
2	
3	
4	
5	



WARNING

If the hearing aid is connected to equipment which is connected to the electrical mains, this equipment must comply with IEC 60065, IEC 60950-1, IEC 60601-1 or equivalent UL safety standards. Do not connect the hearing aid to sockets that are labelled with one or more of the following symbols:



FM systems

A FM system is an assistive listening device that can be used as an accessory for the hearing aid.

We recommend using the FM system from Widex called SCOLA. The FM system consists of a wireless microphone and a receiver clicked onto the hearing aid via a FM shoe.

The SCOLA FM system can be set according to your needs. This may mean that the hearing aid program button will work differently than when using an audio shoe.

For help in determining whether you could benefit from a FM system, please consult your hearing care professional.

IN CASE OF MALFUNCTION

The following pages contain some quick advice on what to do if your hearing aid stops working or performs unsatisfactorily. If the problems persist, contact your hearing care professional for assistance.

See the “Ear-sets for Coselgi™ BTE hearing aids” user manual for information specific to your ear-set.

Problem	Possible cause	Solution
The hearing aid is completely silent	The hearing aid is not turned on	Make sure the battery drawer is pushed all the way upwards
	The battery does not work	Insert a new battery in the hearing aid
The hearing aid volume is not powerful enough	Your ear is blocked by earwax	Contact your ENT doctor/physician
	Your hearing may have changed	Contact your hearing care professional
The hearing aid whistles continuously	Your ear is blocked by earwax	Contact your ENT doctor/physician
The hearing aid functions intermittently	The on/off switch is dirty	Push the switch back and forth a couple of times
Your two hearing aids are not working in synchrony	The connection between the hearing aids is lost	Turn the hearing aids off and on again

Problem	Possible cause	Solution
The hearing aids do not respond with a corresponding change in volume or program to the RC	The RC is used beyond the transmission range	Move the RC closer to the hearing aids
	Strong electromagnetic interference in the vicinity	Move away from known source of EM interference
	The RC battery is dead or does not work	Change the RC battery
	The RC and the hearing aids are not matched	Make sure RC is matched with hearing aids (see User instructions for RC).

CARING FOR YOUR HEARING AID

The hearing aid is a valuable object and should be treated with care. Here are some things you can do to prolong the life of your hearing aid:



CAUTION

- Turn off your hearing aid when it is not in use. Remove the battery if the hearing aid will not be used for several days.
- When the hearing aid is not in use, keep it in its case in a dry location out of reach of children and pets.
- Do not expose the hearing aid to extreme temperatures or high humidity. Make sure to dry the hearing aid thoroughly after heavy perspiration such as that which may occur during intense physical activity, e.g. playing sports.
- Avoid dropping your hearing aid – perform cleaning and battery changes while holding the hearing aid above a soft surface.
- Do not wear your hearing aid while in the shower or swimming, or when using a hair dryer, perfume, hair and body sprays or gels such as suntanning lotions or creams.
- In environments with high humidity, a drying kit may be used daily to reduce the amount of moisture inside the hearing aid. See the instructions enclosed with the drying kit.

WARNINGS



WARNING

Hearing aids and batteries can be dangerous if swallowed or used improperly. Swallowing or improper use can result in severe injury or even fatalities. In case of ingestion, contact a physician immediately and the 24 Hour National Button Battery Ingestion Hotline at (202) 625-3333.

- Keep hearing aids and their parts, accessories and batteries out of reach of children and anyone else who might swallow such items or otherwise cause injury to themselves. Do not change batteries in front of them and do not let them see where you keep your battery supply. Discard used batteries carefully.
- Batteries are very small and can easily be mistaken for pills or the like. Never put a battery or hearing aid in your mouth for any reason as you may risk swallowing it.



WARNING

- Risk of explosion if battery is replaced by an incorrect type or recharged. Dispose of used batteries according to the instructions.
- Never allow others to wear your hearing aid, as this could cause permanent damage to their hearing.
- When selecting a listening program, please remember that there are situations in which it is particularly important to be able to hear the surrounding sounds (e.g. traffic, warning signals).
- The hearing aid is made of modern non-allergenic materials. Nonetheless, in rare cases skin irritation may occur. If you notice skin irritation in or around your ear or ear canal, contact your hearing care professional.



WARNING

- Be aware that the use of any type of hearing aid may involve a slightly increased risk of infection in the ear canal. An infection can arise as a result of inadequate ventilation of the ear. We therefore recommend that you remove the hearing aid and ear-set from your ear at night to allow the ear canal to be ventilated. Make sure that you clean and inspect your hearing aid and ear-set as required. If an infection occurs, you should seek medical attention and contact your hearing care professional for advice on how to disinfect the various hearing aid parts. Do not under any circumstances use alcohol, chlorine or similar substances.
- Do not use the hearing aids in mines or other areas with explosive gases.
- **Do not wear your hearing aid during radiation, X-rays, MRIs, CT or other medical treatments and scans.** The emissions from these procedures as well as from other types of radiation, such as that in a microwave oven, can damage your hearing aid. Radiation from, for example, room surveillance equipment, burglar alarms and cell phones is weaker and will not damage the hearing aid, but may create audible interference.



WARNING

Interference with active Implants

- In order to show caution, we advise to follow the guidelines recommended by manufacturers of defibrillators and pace-makers regarding use of cell phones:
- If you wear an active implantable device keep the Wireless Hearing Aids and Hearing Aid Accessories such as wireless remote controls or communicators at least 15 cm/6 inches away from the implant.
- If you experience any interference, do not use the hearing aids and contact the manufacturer of the implant. Please, note that interference can also be caused by power lines, electrostatic discharge, airport metal detectors etc.
- If you have an active brain implant, please contact the manufacturer of the implant for risk evaluation.

If you have an implantable device, we advise to keep magnets* at least 15 cm/6 inches away from the implant. (*= can be specified as Autophone magnet, hearing instrument case, magnet in a tool, etc.)



CAUTION

- Your hearing aid has been tested for interference according to international standards. Nevertheless, it is possible that unforeseen interference may occur in the hearing aid due to electromagnetic radiation from other products such as alarm systems, room surveillance equipment and cell phones.
- Although your hearing aid has been designed to comply with the most stringent international electromagnetic compatibility standards, the possibility cannot be excluded that it may cause interference with other equipment, such as medical devices.
- Never try to open or repair the hearing aid yourself (Only to be performed by authorized personnel).

ADVICE

NOTE

- The hearing aid will not restore normal hearing and will not prevent or improve a hearing loss resulting from organic conditions. However, the hearing aid can help you to make the best possible use of your remaining hearing ability. You should also bear in mind that it can take time to get used to a new hearing aid and new sounds.
- In most cases, using the hearing aid infrequently will not permit you to gain full benefit from it.
- The use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.
- The use of hearing aids increases the risk of accumulation of earwax. Contact your physician/ENT doctor if you suspect that a plug of earwax has accumulated in your ear. Earwax may not only reduce your own hearing but also the effect of the hearing aid considerably. It is a good idea to ask your physician to clean your ears a couple of times a year.

REGULATORY INFORMATION

The following Table summarizes the technical details of the WidexLink technology as it is implemented in the Melodia™ hearing aids.

	Hearing aids	RC remote control	TM-DEX	Bluetooth* - NOAHlink
Antenna type	Inductive antenna	Inductive antenna	Inductive antenna	Embedded ceramic antenna
Antenna dimensions	Ø1.8 mm, L - 4.85 mm	Ø8 mm, L - 20 mm	Ø6 mm, L - 8 mm	NA
Modulation	FSK	FSK	FSK	FHSS/GFSK, $\pi/4$ DPSK, 8 DPSK
Magnetic Field Strength (at 10 m distance)	-54 dB μ A/m	-13 dB μ A/m	-26 dB μ A/m	NA
Output power (EIRP**)	29 pW	21 nW	1.2 nW	+4dB re. 1mW
Range	< 1 m remote unit to hearing aid < 30 cm between hearing aids or Hearing aid to TM-DEX	< 1 m remote unit to hearing aid	< 30 cm between hearing aid and TM-DEX	< 10 m between PC and NOAHlink
Center frequency	10.6 MHz	10.6 MHz	10.6 MHz	2.4 GHz

	Hearing aids	RC remote control	TM-DEX	Bluetooth* - NOAHlink
Channel	Single channel radio	Single channel radio	Single channel radio	5 logical channels
Bandwidth	660 kHz (-15 dB)	660kHz (-15 dB)	660kHz (-15 dB)	1 MHz
Data-rate	212 kbit/second (raw channel capacity)	212 kbit/second (raw channel capacity)	212 kbit/second (raw channel capacity)	2.1 Mbps
Data flow	Simplex or semi-duplex capability	Simplex capability	Simplex or semi-duplex capability	Time division duplex (TDD)
Protocol	Random Access – no collision avoidance	Random Access – no collision avoidance	Random Access – no collision avoidance	Packet-based protocol, time divided; secure Serial Port Profile (SPP)

* Bluetooth specification v2.0 + EDR published by the Bluetooth Special Interest Group (SIG).

** EIRP = Equivalent isotropically radiated power.

Bluetooth Identifier: B01837

Reference number of QPN: NOAHlinkV1.2_412832_QPN_E1

(Benefits) The use of wireless transmission allows convenient and synchronized control of hearing aid functions. The Melodia wireless hearing aids share input information between the two partner hearing aids. In so doing, the wearers would experience the following additional user benefits (only when wearing binaural Melodia hearing aids).

Synchronization of volume control settings between hearing aids – The volume in both hearing aids will change when the VC is adjusted on one ear.

Synchronization of listening programs between hearing aids – The same listening program is used in both hearing aids when one is changed by the user.

(Contraindications):

- Congenital or traumatic deformity of the ear
- Active drainage from the ear within 90 days
- History of rapid progressive hearing loss within previous 90 days
- Acute or chronic dizziness
- Sudden unilateral hearing loss in previous 90 days

RADIO TRANSMITTER / CABLES / TRANSDUCERS

The Melodia™ series hearing aid contains a radio transmitter / receiver with the following

Radio transmitter parameters:

- Frequency (range): 10.6 MHz (10.2 – 11.0 MHz)
- Bandwidth (-15dB): 660 kHz
- Channel: Single channel radio
- Modulation: FSK
- Radiated output power: 29 pW / -75 dBm
- Magnetic field strength: -54 dB μ A/m @ 10 m
- Duty Cycle: < 5 % (averaged over 1 hour of operation)
- Simplex or semi duplex capability

The radio receiver in the Melodia™ series hearing aid is using the same frequency and bandwidth as the transmitter.



Cables and transducers:

No cables and transducers are used neither during normal use of the Melodia™ series hearing aid nor during programming of the hearing aid.

QUALITY OF SERVICE FOR WIRELESS TECHNOLOGY IN THE WIDEXLINK SYSTEM

WidexLink wireless technology enables communication between two partners of a binaural pair of Melodia hearing aids and with their matched external devices. The requirements for the quality of service (QoS) vary among the various components and their intended user scenarios.

For programming, these requirements include a BER (Bit Error Rate) better than 10^{-3} , at a bitrate of 212 kbits/s, a semi-duplex transmission with a required acknowledge, a transmission latency in each direction (2x) and a receive-to-transmit mode (RX to TX) time. The data are saved in the hearing aid even when transmission is interrupted.

During daily use, the requirements on audio streaming between hearing aids include a BER better than 10^{-3} . The communication is simplex with a bitrate of 212 kbits/s. The additional audio decoding in this mode results in a longer latency which is less than 10 ms. For remote control commands the QoS requirements include a BER better than 10^{-2} . The lower BER requirement results from redundant transmissions. Each key press results in transmissions of 7 data packages of which only one is needed for a successful communication.

For inter-ear communication between hearing aids, a BER better than 10^{-3} is required. The communication is updated every 50 ms (or 20 Hz). The hearing aids continue to amplify based on the last saved settings even when the transmission range is exceeded or when communication is interfered.

Wireless Security Measures

Security of the wireless signals is assured through device system design that includes:

- Individual MAC address for each unit which is checked during each transmission.
- A built-in pairing table which specifies valid and legitimate pairing among units
- A proprietary communication protocol which checks the package numbers during each transmission.
- A Cyclic Redundancy Check (CRC) to check data validity and correct errors.

GUIDANCE AND MANUFACTURER'S DECLARATION

Electromagnetic emissions

The Melodia™ series hearing aids are intended for use in the electromagnetic environment specified below. The customer or the user of a Melodia™ series hearing aid should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Melodia™ hearing aid uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Melodia™ hearing aid is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable *)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable *)	

*) *Battery powered equipment*

Electromagnetic immunity

The Melodia™ series hearing aids are intended for use in the electromagnetic environment specified below. The customer or the user of a Melodia™ series hearing aid should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transients/burst IEC 61000-4-4	± 2 kV for power line supplies ± 1 kV for input/output lines	Not applicable *) Not applicable *)	Not applicable *)
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable *) Not applicable *)	Not applicable *)

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Not applicable *)	Not applicable *)
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment


NOTE U_T is the a.c. mains voltage prior to the application of the test level.

*) *Battery powered equipment*

Electromagnetic immunity – cont.

The Melodia™ series hearing aids are intended for use in the electromagnetic environment specified below. The customer or the user of a Melodia™ series hearing aid should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Melodia™ series hearing aid, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
			<p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a, should be less than the compliance level in each frequency range ^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Melodia™ series hearing aid is used exceeds the applicable RF compliance level above, the Melodia™ series hearing aid should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or re-locating the Melodia™ series hearing aid.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances

Recommended separation distances between portable and mobile RF communication equipment and the Melodia™ series hearing aids.

The Melodia™ series hearing aids are intended for use in the electromagnetic environment in which RF disturbances are controlled. The customer or the user of the Melodia™ series hearing aid can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Melodia™ hearing aids as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electro-magnetic propagation is affected by absorption and reflection from structures, objects and people.

This Melodia™ hearing aid may be interfered with by other equipment even if that other equipment complies with CISPR emission requirements.

(EMI/EMC Compliance).

The Melodia™ hearing aid complies with the following EMC/EMI standards:

Standard	Test type	Note
47 CFR Part 15, subpart C	RF emissions	USA Federal Communications Commission (FCC) requirements for intentional radiators.
EN 300 330-2 V1.5.1	RF emissions incl. Spurious emission	EMC and radio spectrum matters for Short Range Devices in the frequency range 9 kHz – 25 MHz
IEC 60601-1-2:2007 *adapted protocol	EMC emission Immunity, RF and ESD	Medical electrical equipment. General requirements for basic safety and essential performance. Electromagnetic compatibility.
EN 301 489-3 V1.4.1	Immunity, RF and ESD	Standard for Low Power Transmitters in the frequency range 9 kHz – 40 GHz
IEC 60118-13:2011	Immunity RF Near Field immunity test	International Product std. for hearing aids to ensure adequate immunity to radio interference from cell telephones.
ANSI C63.19:2007	Immunity RF Near Field immunity test	American National Standard Methods of measurement of Compatibility between wireless Communication Devices and Hearing Aids

** The device was tested in only one orientation that represents the longest length (or worst case scenario). This is acceptable because of the relative small size of the device compared to the wavelength of the RF used in the test.*

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists, or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

Children with hearing loss

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

FCC ID: TTY-C49

IC: 5676B-C49

Federal Communications Commission Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

NOTE:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Changes or modifications to the equipment not expressly approved by Coselgi could void the user's authority to operate the equipment.

Industry Canada Statement / Déclaration d'industrie Canada

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada.

To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions:

- (1) this device may not cause interference, and
- (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada.

Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

- (1) l'appareil ne doit pas produire de brouillage, et
- (2) l'utilisateur de l'appareil doit accepter tout brouillage radio-électrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

CE 0459

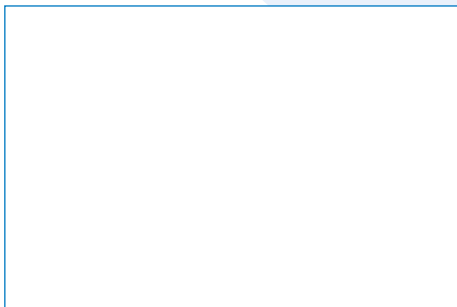
Hereby, Coselgi A/S declares that this CMe-BTE is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

A copy of the Declaration of Conformity can be found at: <http://www.coselgi.com/products/doc>

 **N26346**



Hearing aids, accessories and batteries should not be disposed of with normal household waste. Please consult your national Coselgi distributor for advice on how to dispose of these items.



CE 0459

Manufacturer

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